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EXAMINER
PROUTY, R

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ART UNIT	PAPER NUMBER
1814	

DATE MAILED: 01/27/93

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☒ Responsive to communication filed on 10/8/92 ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), — days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☐ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice re Patent Drawing, PTO-948.
3. ☐ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, Form PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☒ Interview Summary

Part II SUMMARY OF ACTION

1. ☒ Claims 1-39 are pending in the application.
   Of the above, claims 1-11, 14, 27-29, 32-34 and 36-39 are withdrawn from consideration.
2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 12, 15-26, 30 and 35 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable. ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____ has (have) been ☐ approved by the examiner. ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed on _____, has been ☐ approved. ☐ disapproved (see explanation).
12. ☐ Acknowledgment is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

PTOL-326 (Rev. 9-89)

The previous final rejection of Claims 12-13, 23-26 and 30 and the previous indication of allowability of Claims 15-22 and 35 are withdrawn in light of the following rejections to the claims.

Claims 1-39 are currently pending in this case. Applicant's election of Group II, Claims 1, 13, 15-26, 30 and 35 in Paper No. 5 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (M.P.E.P. § 818.03(a)). Claims 1-11, 14, 27-29, 31-34 and 36-39 remain withdrawn from further consideration by the examiner, 37 C.F.R. § 1.142(b) as being drawn to a nonelected invention. Election was made **without** traverse in Paper No. 5.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to adequately teach how to make the claimed invention. Claim 23 claims polypeptide fragments and analogs of metalloproteinase inhibitor (M1). This term is so broad as to include virtually any type of modification known, including insertions, deletions, mutations, and chemical

modifications. No guidance is provided as to what portions of the disclosed protein can be modified without changing the activity of the protein nor of what types of modifications are likely to produce an active protein. Therefore, undue experimentation would be required of one skilled in the art to make fragments and analogs of the MI protein disclosed. Furthermore, Claims 12, 13, 15-18, 21-22, 25-26 and 30 are currently sufficiently broadly stated as to also include fragments and virtually any analogs of human MI.

Claims 12, 13, 15-18, 21-26 and 30 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification. It is suggested that all of these claims be limited to read on only the DNA encoding the amino acid sequence of the entire human MI protein shown in Figure 2.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same

person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

Claims 12, 13, 23-26 and 30 are again rejected under 35 U.S.C. § 103 as being unpatentable over Murray et al. in view of Kimmel for the reasons made of record in the previous office action as these claims are not limited to the expression of human MI and the combined disclosures of Murray et al. and Kimmel make obvious the cloning and expression of the gene for the bovine MI protein disclosed by Murray et al. Applicant should note that the amendment to Claim 12 (from which all of these claims depend) filed under 37 CFR 1.116 on 12/8/92 has not been entered in this case but entry of this amendment would not overcome the previous rejection because bovine MI, as taught by Murray et al., clearly has at least a part of the primary structural conformation (defined as having an amino acid sequence at its amino terminus of at least amino acid residues 1 to 42 of Figure 2) and all of the biological properties of naturally occurring MI and will hybridize under stringent conditions to the gene for human MI.

Claims 15-22 and 35 are allowable over the prior art of record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rebecca Prouty, Ph.D., whose telephone number is (703) 308-4000.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

ROBERT A. WAX
SUPERVISORY PATENT EXAMINER
GROUP 180